

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
LINDA E. HALL
GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, UW2220
709 SWEDELAND ROAD, P.O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

PCT

REC'D 08 DEC 2005

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference PU60698		Date of mailing (day/month/year) 05 DEC 2005 FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US05/02121	International filing date (day/month/year) 21 January 2005 (21.01.2005)	Priority date (day/month/year) 23 January 2004 (23.01.2004)
International Patent Classification (IPC) or both national classification and IPC IPC(7): C07D 401/00 and US Cl.: 540/597		
Applicant SMITHKLINE BEECHAM CORPORATION		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

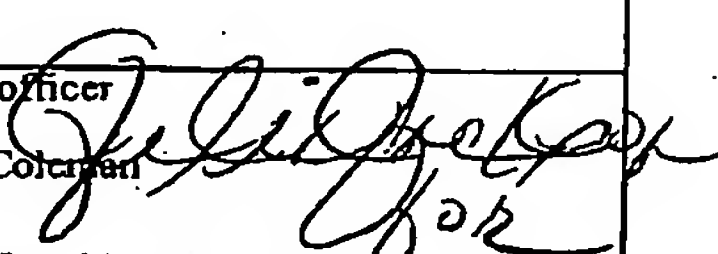
2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 14 November 2005 (14.11.2005)	Authorized officer Brenda L. Coleman  Telephone No. 571-272-1600
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Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/02121

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/02121

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-43</u>	YES
	Claims <u>44</u>	NO
Inventive step (IS)	Claims <u>1-43</u>	YES
	Claims <u>44</u>	NO
Industrial applicability (IA)	Claims <u>1-44</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claim 44 lacks novelty under PCT Article 33(2) as being anticipated by WO 2001/070232 A1 (SMITHKLINE BEECHAM CORPORATION). WO 2001/070232 teaches the benzofuran-2-carboxylic acid {(S)-1-[(3S,4S,7R)-3-hydroxy-7-methyl-1-1(pyridine-2-sulfonyl)-azepan-4-ylcarbamoyl]-3-methyl-butyl}-amide compound of the instant invention. See lines 1-2 on page 57.

Claim 44 lacks an inventive step under PCT Article 33(3) as being obvious over WO 2001/070232 A1 (SMITHKLINE BEECHAM CORPORATION). For reasons stated above.

Claims 1-43 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the process of preparing the compounds of formulae I and II and the intermediates as claimed herein.

Claims 1-43 meet the criteria set out in PCT Article 33(4), and thus the process of preparing the compounds of formulae I and II and the intermediates have industrial applicability because the subject matter claimed can be made or used in industry.

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FOR FURTHER ACTION

See paragraph 2 below

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IPC(7): C07D 401/00 and US Cl.: 540/597

Applicant

SMITHKLINE BEECHAM CORPORATION

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Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Date of completion of this opinion
14 November 2005 (14.11.2005)

Authorized officer
Brenda L. Coleman
Telephone No. 571-272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

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